DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 2, 2015

Implant Microdent
c/o Ms. Rhonda Alexander, M.S., M.P.A.
Registrar Corp
144 Research Drive
Hampton, VA 23666

Re: K141188
Trade/Device Name: Microdent Genius Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 1, 2015
Received: May 4, 2015

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141188

Device Name
Microdent Genius Implant System

Indications for Use *(Describe)*
Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.
Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY (21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

The assigned 510(k) number is: K141188

Premarket Notification [510(k)] Summary

A. General Information

Submitter's Name: Implant Microdent Systems
Address: C/ Carles Buigas, 1 – Can Magre
Sta Eulalia de Ronçana
Barcelona, Barcelona E-08187
Spain

Telephone: +34-902-402-420
Fax Number: +34-94-844-7893
Contact Person: Jordi Clapes Donadeu

Date Prepared: March 1, 2013

B. Device

Trade Name: Microdent Genius Implant System
Classification Name: Endosseous Dental Implants
Product Code: DZE and NHA
Class: II
Regulation Number: 21 CFR 872.3640

C. Identification of Legally Marketed Predicate Device

ANKYLOS C/X Dental Implant – K083805 (primary predicate)
ANKYLOS Balance Base abutment C/ – K041509 (reference predicate)
XiVE Dental Implant System (Ball and Socket Attachment) – K021318 (reference predicate)

D. Description of the Device

Microdent Genius Implant System is comprised of dental implants and prosthetic components. Microdent Genius dental implants are internal connection endosseous implants machined titanium that can be used with deferred load or immediate load techniques. If sufficient bone depth is available the implant can be inserted sub-crestal. Microdent Genius Implant is recommended to place 2mm sub-crestal position.

The implant has a connection formed by six grooves extending radially around the axis of the implant to provide a precise position of the abutment.

Microdent Genius Implants are provided with blasted surface.

The implants are supplied sterile and the abutments are provided non-sterile.

- Implants are also offered in various diameters and length.

Ø platform	Ø core	Length	Reference
3.50	3.50	8	GN3508
		10	GN3510
		12	GN3512
		14	GN3514
		16	GN3516
		18	GN3518
4.00	4.00	8	GN4008
		10	GN4010
		12	GN4012
		14	GN4014
		16	GN4016
		18	GN4018
4.50	4.50	8	GN4508
		10	GN4010
		12	GN4512
		14	GN4514
		16	GN4516
		18	GN4518
5.00	5.00	8	GN5008
		10	GN5010
		12	GN5012
		14	GN5014
		16	GN5016

- Contained various Microdent Genius abutments made of Ti-6AL 4-V-ELI alloy.

The abutments Conical, Angled and Mini Capitel are used for cemented and screw-retained restorations.

Conical abutment with flap:

GNPCCP4501H	Microdent Genius hex. Conical with flap abutment	Ø 4.50 Height 1 to 6 mm
GNPCCP5001H	Microdent Genius hex. Conical with flap abutment	Ø 5.00 Height 1 to 6 mm
GNPCCP5501H	Microdent Genius hex. Conical with flap abutment	Ø 5.50 Height 1 to 6 mm
GNPCCP4501R	Microdent Genius Circular Conical with flap abutment	Ø 4.50 Height 1 to 6 mm
GNNPCCP5001R	Microdent Genius Circular Conical with flap abutment	Ø 5.00 Height 1 to 6 mm
GNPCCP5501R	Microdent Genius Circular Conical with flap abutment	Ø 5.50 Height 1 to 6 mm

Conical abutment without flap:

GNPCSP38H	Microdent Genius Hex. Conical without flap abutment	Ø 4.50 Height 1 to 6 mm
GNPCSP43H	Microdent Genius Hex. Conical without flap abutment	Ø 5.00 Height 1 to 6 mm
GNPCSP48H	Microdent Genius Hex. Conical without flap abutment	Ø 5.50 Height 1 to 6 mm

Immediate loading conical abutment:

GNPCI4501H	Microdent Genius hex. immediate loading conical abutment	Ø 4.50 Height 1 to 6 mm
GNPCI5001H	Microdent Genius Hex. Conical without flap abutment	Ø 5.00 Height 1 to 6 mm
GNPCI5501H	Microdent Genius Hex. Conical without flap abutment	Ø 5.50 Height 1 to 6 mm
GNPCI4501R	Microdent Genius circular immediate loading conical abutment	Ø 4.50 Height 1 to 6 mm
GNPCI5001R	Microdent Genius circular immediate loading conical abutment	Ø 5.00 Height 1 to 6 mm
GNPCI5501R	Microdent Genius circular immediate loading conical abutment	Ø 5.50 Height 1 to 6 mm

Angled abutment:

GNPAE154501H	Microdent Genius hex Aesthetic Angled Abutment 15º	Ø 4.50 Height 1 to 5 mm
GNPAE204501H	Microdent Genius hex Aesthetic Angled Abutment 20º	Ø 4.50 Height 1 to 5 mm
GNPAE254501H	Microdent Genius hex Aesthetic Angled Abutment 25º	Ø 4.50 Height 1 to 5 mm
GNPAE155001H	Microdent Genius hex Aesthetic Angled Abutment 15º	Ø 5.00 Height 1 to 5 mm
GNPAE205001H	Microdent Genius hex Aesthetic Angled Abutment 20º	Ø 5.00 Height 1 to 5 mm
GNPAE255001H	Microdent Genius hex Aesthetic Angled Abutment 25º	Ø 5.00 Height 1 to 5 mm
GNPAE155501H	Microdent Genius hex Aesthetic Angled Abutment 15º	Ø 5.50 Height 1 to 5 mm
GNPAE205501H	Microdent Genius hex Aesthetic Angled Abutment 20º	Ø 5.50 Height 1 to 5 mm
GNPAE255501H	Microdent Genius hex Aesthetic Angled Abutment 25º	Ø 5.50 Height 1 to 5 mm
GNPASP3815H	Microdent Genius hex Angled without flap Abutment 15º	Ø3.8 Height 0 mm
GNPASP3820H	Microdent Genius hex Angled without flap Abutment 20º	Ø3.8 Height 0 mm
GNPASP3825H	Microdent Genius hex Angled without flap Abutment Ø 3.80 25º	Ø3.8 Height 0 mm
GNPASP4315H	Microdent Genius hex Angled without flap Abutment 15º	Ø4.3 Height 0 mm
GNPASP4320H	Microdent Genius hex Angled without flap Abutment 20º	Ø4.3 Height 0 mm
GNPASP4325H	Microdent Genius hex Angled without flap Abutment 15º	Ø4.3 Height 0 mm
GNPASP4815H	Microdent Genius hex Angled without flap Abutment 15º	Ø4.8 Height 0 mm
GNPASP4820H	Microdent Genius hex Angled without flap Abutment Ø 20º	Ø4.8 Height 0 mm
GNPASP4825H	Microdent Genius hex Angled without flap Abutment 25º	Ø4.8 Height 0 mm

Mini Capitel abutment:

GNCAPN4801R	Microdent Genius Circular Mini Capitel Abutment	Ø 4.80 Height 1 to 6 mm
GNCAPNA 174801H	Microdent Genius Hex Angled Mini Capitel abutment 17º	Ø 4.80 Height 1 to 2 mm
GNCAPNA 304801H	Microdent Genius Hex Angled Mini Capitel abutment 30º	Ø 4.80 Height 1 to 2 mm
UTSNPC4X	Microdent Genius Mini Capitel cementable coping	Ø 4.80
UTSNCP4X	Microdent Genius Mini Capitel Protective Cap	Ø 4.80

- A Cover screw protects the inner configuration of the implant and supplied sterile with the implant.

- Healing abutment to shape the soft tissue during the healing phase.

GNPR4501	Microdent Genius Healing abutment	Ø 4.50 Height 1 to 6 mm
GNPR5001	Microdent Genius Healing abutment	Ø 5.00 Height 1 to 6 mm
GNPR5501	Microdent Genius Healing abutment	Ø 5.50 Height 1 to 6 mm
GNPCR3501	Microdent Genius Healing abutment	Ø 3.50 Height 1 to 6 mm

- The Retention Screws are used for securing the abutments to the implant.

- Overdenture retention consists of a titanium alloy socket that attached to a threaded post for use with titanium endosseous implants having an internal threaded socket. Both devices have a plastic component that has a shape on one and that mate into the titanium socket, while the other end with metal cap is attached to the denture.

GNEOSS3500	Microdent Genius Osscilia retention abutment	Ø 3.50 Height 0 to 6 mm
CSUTGOSS	Metal cap with soft, middle and strong Osscilia retainer.	Titanium grade 5 +POM

All abutments include appropriate features and dimensions to mate with Microdent Genius implants.

E. Intended Use

Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.
Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.

F. Summary of Testing and Comparison to the Predicate Device

The devices are designed and manufactured in accordance with the following standards:

ISO 5832-2:1999 Implants for surgery - Metallic materials - Part 2: Unalloyed titanium
ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices
ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity

USP 37th ed. 2014<85> Bacterial Endotoxins Test

USP 37th ed. 2014<151> Pyrogen Test

ISO 14698-1:2003 Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1: General Principles and Methods

ISO 14644-1:1999 Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness

ISO 14644-3:2005 Cleanrooms and associated controlled environments - Part 3: Test methods

ISO 11737-1:2006 (R)2011 Sterilization of medical devices - Microbiological methods Part 1: Determination of the population of microorganisms on product, 2ed

ISO 11737-2:2009 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

ISO 11607-1:2006/(R)2010 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-2:2006/(R)2010 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

ISO 11137-1:2006/(R) 2010 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

ISO 11137-2:2012 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

ISO 11137-3:2006/(R)2010 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects.

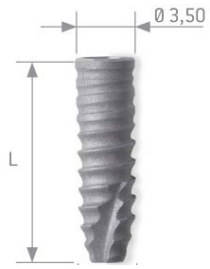
ASTM F1980-07 (Reapproved 2011), Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices. (Sterility).

ANSI / AAMI ST79: 2010& A1:2010 & A2:2011 & A3:2012 & A4:2013 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Comparison of Technological Characteristics

Table 1: General Implant Device Comparison

Characteristic	Subject Device	Predicate Device	SE / Comments
• Device Name	Microdent Genius implant	ANKYLOS C/X Implant	yes
• 510K	NA	K083805	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches,	The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and	Yes (Genius Microdent specified the use

	for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.	of small diameter implants)
• material	Comercially pure titanium (grade 4 as ISO 5832-2)	Comercially pure titanium (grade 2 as ISO 5832-2)	Yes (different degree but with very similar properties)
• design;	Parallel-walled and threaded. 	Same 	yes
• length (mm)	8, 10, 12, 14, 16 and 18 mm.	8, 9.5, 11, 14 and 17 mm	yes
• diameter (mm)	Diameter ranges: 3.5 mm, 4.0 mm, 4.5 mm and 5.00 mm.	Diameter ranges: 3.5 mm, 4.5 mm, 5.5 mm and 7.0 mm.	Yes (ANKYLOS also has a diameter of 7.0 mm)
• connection type	Internal connection tapered with indexation.	Internal connection tapered with indexation.	yes

• surface treatment	Blasting (roughness 0,82 µm peak-to-valley).	Grit-blasted sand high-temperature etched (roughness 2,75 µm peak-to-valley).	yes (different treatment with similar result)
• sterilization	Sterile (Gamma irradiation)	same	yes
• Packaging	Packaged with sterile vial with cover screw	Packaged with sterile blister with cover screw	yes
• Shelf Life	5 years	5 years	yes
• Mating Components	All Microdent Restorative Components	All ANKYLOS C/X Restorative Components	yes

Table 2: General Prosthetic Device Comparison

Characteristic	Subject Device	Predicate Device	SE / Comments
• Device Name	Microdent Genius implant abutments	ANKYLOS C/X Implant abutments	yes
• 510K	NA	K083805	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral	The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.	Yes (Genius Microdent specified the use of small diameter implants

	incisors in the maxillar and mandible.	Multiple tooth applications may be splinted with a bar.	
• material	Titanium alloy (Grade 5).	same	yes
• surface treatment	Polished.	same	yes
• sterilization	No sterile	same	yes
• Packaging	Blister	same	yes
• Device Name	Microdent Genius Cover Screw	ANKYLOS Cover Screw	yes
• 510K	NA	K083805	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.	Yes (Genius Microdent specified the use of small diameter implants
• design;	One diameter and metric thread M1.8	One diameter and metric thread M1.8	yes
• Collar Height (mm, min -max)	Without heights	Without heights	yes
• Seating Surface (mm)	Diameter 2.9 mm.	Diameter 2.48 mm.	yes
• connection type	Internal connection tapered.	Internal connection tapered.	yes
• sterilization	Sterile (Gamma irradiation)	same	Yes. Packaged sterile with the implant

• Device Name	Microdent Genius Healing Abutment	Ankylos Regular C/X Gingiva Former	yes
• 510K	NA	K083805	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.	Yes (Genius Microdent specified the use of small diameter implants
• design;	3 diameters and metric thread M1.8	One diameter and metric thread M1.8	yes
• Collar Height (mm, min -max)	1 mm to 6 mm	0.75, 1.5, 3 and 4,5 mm	yes
• Seating Surface (mm)	Diameter from 4.5, 5 and 5.5 mm.	Diameter 5.5 mm.	yes
• connection type	Internal connection tapered.	Internal connection tapered with indexation (/X) or only tapered (C/)	yes
• Device Name	Microdent Genius Retention screw	Ankylos Fixation screw	yes
• 510K	NA	K083805	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant	The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X	Yes (Genius Microdent specified the use of small diameter implants

	System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.	
• design;	This screw having a threaded fuse and a head with a hexagon 1.20 mm flat to flat.	Similar geometry with hexagon 1.00 mm.	yes
• Seating Surface (mm)	This is a single Retention screw for all platforms	same	yes
• Device Name	Microdent Genius Conical abutment	Ankylos Regular C/X abutment and Ankylos SynCone C/	yes
• 510K	NA	K083805 K041509	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.	Yes (Genius Microdent specified the use of small diameter implants
• design;	3 diameters and same connection (Microdent Genius)	One diameter and Ankylos connection	yes
• Collar Height (mm,	1 mm to 6 mm	0.75, 1.5, 3 and 4,5	yes

min -max)		mm	
• Seating Surface (mm)	Diameter from 4.5, 5 and 5.5 mm.	Diameter 5.5 mm.	yes
• connection type	Internal connection tapered with indexation (H) or only tapered (C).	Internal connection tapered with indexation (/X) or only tapered (C/)	yes
• Device Name	Microdent Genius Angled abutment	Ankylos Regular C/X abutment	yes
• 510K	NA	K083805	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.	Yes (Genius Microdent specified the use of small diameter implants
• design;	3 diameters and same connection (Microdent Genius). 3 angulations 15º, 20º and 25º. With flap (aesthetics) and without flap.	One diameter and Ankylos connection. 5 angulations 7.5º, 15º, 22.5º, 30º and 37.5º. With flap.	Yes Without flap provides shoulder prosthesis occultation in cases of low gingiva.
• Collar Height (mm, min -max)	1 mm to 5 mm	0.75, 1.5, 3 and 4,5 mm	yes

• Seating Surface (mm)	Diameter from 4.5, 5 and 5.5 mm.	Diameter 5.5 mm.	yes
• connection type	Internal connection tapered with indexation (H).	Internal connection tapered with indexation (/X) or only tapered (C/).	yes
• Device Name	Microdent Genius Mini Capitel abutment	Ankylos Balance Base abutment C/	yes
• 510K	NA	K041509	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	An endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on 4 interforminal placed implants, and not indicated for single, unsplinted implants. Patients must be subject for dental treatment with endosseous implants.	Yes (Genius Microdent specified the use of small diameter implants. Ankylos Balance Base restricted the immediate loading to the anterior mandible, based 4 interforminal placed implants.
• design;	One prosthetic diameter of 4,8 mm. Angulations of 17º and 30º.	One prosthetic diameter of 4,2 mm. Angulations of 15º and 30º.	yes
• Collar Height (mm, min -max)	1 mm to 6 mm	0.75, 1.5, 3 and 4,5 mm	yes

• Seating Surface (mm)	Diameter 4.8 mm.	Diameter 4.2 mm.	yes
• connection type	Internal connection tapered (C).	Internal connection tapered (C/)	yes
• Copings	Cementable coping of Titanium (Grade 5)	Two cementable coping of Gold alloy.	yes
• Device Name	Microdent Genius Osscilia retention abutment	XiVE Ball and Socket Abutment Ankylos Snap abutment C/.	yes
• 510K	NA	K021318 K083805	
• intended use/ indications for use	Microdent Genius Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Microdent Genius Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Small diameter implants are indicated only for replacement of central and lateral incisors in the maxillar and mandible.	The XiVE@ Dental Implant System is indicated as follows: once the implant has osseointegrated, it serves to support single tooth, bridge and overdenture restorations. In the edentulous mandible, a minimum of four XiVE dental implants (>9.5mm length) are placed between the mental foramina and rigidly splinted together. In this case, bar-prosthetic loading is possible immediately after implant placement. The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate	Yes (but Genius Microdent specified the use of small diameter implants. The use of XiVE@ Dental Implant System in mandible restricted a minimum of four XiVE dental implants (>9.5mm length) are placed between the mental foramina).

		occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.	
• design;	One prosthetic diameter of 3.5 mm. Compensation 17º.	One prosthetic diameter of 3.1 mm. Compensation 20º.	Yes XiVE Abutment consists of two parts, one which has the geometry of the implant connection and over the axis of the abutment. This characteristic differs from Genius and Ankylos but isn't relevant.
• Collar Height (mm, min -max)	1 mm to 6 mm	1.5, 3 and 4,5 mm	yes
• Seating Surface (mm)	Diameter 3.5 mm.	Diameter 3.1 mm.	yes
• connection type	Internal connection tapered (C).	Internal connection tapered (C/)	yes

Microdent Genius Implant System is substantially equivalent intended use as the identified predicates. Microdent Genius Implant System is similar in fundamental scientific technology to the predicate devices in that they all have been designed, manufactured and tested in compliance with FDA'S Class II special controls guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

Microdent Genius Implant System is substantially equivalent in materials, indications and intended use, packaging, labeling and performance to the predicate devices currently marketed in the U.S.

The only differences the subject device and the predicate are slight differences in design and dimensions.

Non-Clinical performance tests

The proposed devices have been subject to bench testing to determine fulfillment of design and performance requirements. Bench testing followed the recommendations provided in FDA Guidance Document – Class II Special Controls Guidance Document for Endosseous Dental

Implants and Endosseous Dental Implant Abutments and included static and dynamic fatigue testing in accordance with ISO 14801. Biocompatibility testing has been performed and ESEM/EDS analyses to determine adequate surface finish and cleaning. Package integrity testing and sterilization validation have been performed.

G. Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the decision of substantial equivalent.

H. Conclusion of Substantial Equivalence

Based on the similarities observed and results of non-clinical testing performed, we conclude that the proposed devices are substantially equivalent to the predicate devices.